PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2003015-WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK2004/000204	International filing date *(day/month/year)* 24.03.2004	Priority date *(day/month/year)* 28.03.2003
International Patent Classification (IPC) or both national classification and IPC A61L15/28, A61L15/44, A61L15/60		
Applicant COLOPLAST A/S et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☒ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28.01.2005	11.08.2005
Name and mailing address of the International preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Böhm, I Telephone No. +31 70 340-1050

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK2004/000204

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-12 as originally filed

Claims, Numbers

1-10 received on 01.02.2005 with letter of 01.02.2005

Claims, Pages

13, 14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

II. Priority

1. ☒ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

   ☒ copy of the earlier application whose priority has been claimed.

   ☐ translation of the earlier application whose priority has been claimed.

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

   Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-10
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-10
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item I.
Basis of the opinion

This report has been established as if some of the amendments had not been made, since they have been considered to go beyond the disclosure as filed. (Rule 70.2(c))

The following amendments have been sent (Article 34(2) b)):
Claims 1-10 : "a wound dressing" -> "a lightweight wound contacting layer"
Claim 1 : "and the density of the reinforcing layer is in the range of 15 to 40 g/m^2."

The term "lightweight" is supported by the description as originally filed and therefore acceptable.
The expression "wound dressing" is a general term comprising different layers, such as a "wound contacting layer". The term "wound contacting layer" has not explicetely mentioned in the description as originally filed. Therefore this change, although limiting, but not originally disclosed is in contradiction to Article 34(2) b) PCT and goes beyond the disclosure as originally filed.

This introduction of a "layer" instead of using the term "dressing" results in doubts concerning present claims 7 and 10. They refer to a "layer comprising one or more active ingedients/ Ag-Ca-Alginate and/or Ag-Na-CMC".
The claims stand on their own and in this case, it is not unambiguously clear in which layer the active ingredients are comprised.

The mentioned density-range of the reinforcing layer claimed in the newly filed claim 1 has been disclosed originally on p.7, lines 15,16 as a preferred embodiment.

Re Item V.

1 The following document has been referred to in this communication:
D1 : GB 2 377 177 A (ACORDIS SPECIALITY FIBRES LTD) 8 January 2003 (2003-01-08)

2 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-10 is not new in the sense of Article 33(2) PCT.
Document D1 discloses a wound dressing suitable for use on bleeding wounds.
The wound dressing comprises a layer of a low adherent gel-forming fabric backed by a layer of a material having a superabsorbent component. The gel-forming fabric is haemostatic and preferably an alginate.
The basis weight of the alginate fabric is in the range from 25 to 200 g/m^2.
The alginate fibre is typically calcium alginate or sodium calcium alginate. The alginate fibre contain therapeutically-active metal ions, such as silver. The alginate fibre may be medicated, such as comprising anti-bacterial agents. The alginate-containing face of the dressing is placed against the wound.
The alginate dressing of D1 has low adherence to wounds and can be easily removed therefrom without causing trauma and without leaving dressing fragments in the wound.
The dressing may be a unitary fabric formed by needlepunching together webs of alginate fibre and of a fabric containing a surperabsorbent fibre.
The superabsorbent layer may include a low melting point polymer so that the layers can be thermally bonded together.
(see p.1-3 entirely)
The dressing of D1 may additionally comprise a liquid-impermeable and breathable backing layer and means for attachment to a patient, such as an adhesive layer extending beyond the alginate fabric. (see p.3, lines 12-14)
The present application, the reinforcing layer has been described : "The reinforcing layer may be any suitable layer providing the dressing with desired properties with regard to strength and permeability. It may be in the form of a net, a foam, a film, a knit, a non-

woven or woven material."
Therefore the liquid-impermeable and breathable backing layer of D1 fullfils the requirements for being a reinforcement layer as claimed in the present claims.

As mentioned in the description of the present application on p.2, lines 16 and 17, describing the content of D1 as "...the dressing is thick and is designed for heavy exuding wounds, due to high absorbency."
It goes without saying, that neither independent claim 1 of the present application nor any further claim exclude a thick dressing nor a dresing "designed for heavy exuding wounds".
The subject-matter of claim 1 for which protection is sought, has been specified as a web of gel-forming fibers, attached to a reinforcing layer wherein the density of the web is 5-60 g/m^2 and the density of the reinforcing layer is in the range of 15 to 40 g/m^2.
Claim 1 is not limited to a specified thickness or to a specified kind of application on less bleeding wounds.
Nevertheless, a wound dressing showing the same composition, construct and properties, should be suitable for the same purpose.
D1 has been still considered as novelty destroying for the subject-matter of claims 1-10. (see Article 33(1) and (2) PCT)

3. DEPENDENT CLAIMS 2-10
Dependent claims 2-10 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

The subject-matter which has been already destroyed by novelty cannot be considered to be inventive, because there is no contribution to the prior art.

Claims:

1. A lightweight wound contacting layer comprising a web of gel-forming fibers or fibers soluble in wound exudates, attached to a reinforcing layer wherein the density of the web is in the range of 5-60 g/m^2 and the density of the reinforcing layer is in the range of 15 to 40 g/m^2.

2. A lightweight wound contacting layer according to claim 1 wherein the fibers are selected from the group consisting of polysaccharide or polyacrylate fibers, preferably alginate, chitosan, alginate containing CMC, or CMC fibers or derivatives or mixtures thereof.

3. A lightweight wound contacting layer according to claim 1 or 2 wherein the web is attached to the reinforcing layer by needling.

4. A lightweight wound contacting layer according to any of claims 1-3 wherein the web is attached to the reinforcing layer by thermal bonding.

5. A lightweight wound contacting layer according to any of claims 1-4 wherein the web is attached to the reinforcing layer by adhesive means.

6. A lightweight wound contacting layer according to any of claims 1-5, wherein the reinforcing layer is in the form of a net, a foam, a film, a non-woven or woven material.

7. A lightweight wound contacting layer according to any of claims 1-6 wherein the layer comprises one or more active ingredients.

8. A lightweight wound contacting layer according to claim 7 wherein the active ingredient comprises an antibacterial agent.

9. A lightweight wound contacting layer according to claim 7 wherein the active ingredient comprises a pain-relieving agent.

10. A lightweight wound contacting layer according to any of claim 1-9 wherein the layer comprises Ag-Ca-alginate and/or Ag-Na-CMC.